REMARKS

Claims 1 – 13 are pending in this application.

Claims 1 - 11 have been rejected.

Claims 12 and 13 are new.

Amendments to the Specification

The specification has been amended in Table II and paragraphs [43], [45] and [46]. All changes derive from a minor miscalculation and typographical error in Table II, in which the Total Rate of Timeslot 5 was multiplied by three hours, rather than the two hours indicated in Time of Day of Timeslot 5. Thus, Drug Delivered should have been 35 mg/hr * 2 hr = 70 mg, and not 105 mg as originally calculated. Thus, all future references to Table II in paragraphs [43], [45] and [46] used figures based on that miscalculation, and needed to be corrected. No new matter has been added.

Amendments to the Claims

Claim 1 has been amended to clarify the claim by more clearly laying out the steps of the method. The manually programming step now programs a maximum dose, a basal rate and a plurality of interval rates over a specified time period, with each interval rate corresponding to a time interval over the specified time period (lines 4 – 7). The system then determines a total dose over the specified time period in the determining step, based on the basal rate and the interval rates (lines 8 – 10). The system then adjusts the basal rate in the adjusting step so that the total dose does not exceed the maximum dose (lines 11 – 12). The delivering step delivers the fluid medication based on the adjusted basal rate and the plurality of interval rates (lines 13 – 15). This amendment is supported in paragraphs [27] – [32], [36] – [37], [44] and [46]. No new matter has been added.

Claim 3 has been amended to make the claim consistent with amended independent claim 1. As amended, both claims 1 and 3 now refer to a plurality of interval rates. No new matter has been added.

Claim 12 has been added to claim the programming step occurring before the beginning of the specified period of time. This amendment is supported in paragraph [54] of the specification. No new matter has been added.

Claim 13 has been added to claim a method whereby the basal rate is adjusted based on a determined total dose and changes to the plurality of interval rates. The manually programming step now programs a basal rate and a plurality of interval rates over a specified time period, with each interval rate corresponding to a time interval over the specified time period (lines 4 – 7). The determining step then determines a total dose over the specified time period based on the basal rate and the interval rates (lines 8 – 9) The manually adjusting step then adjusts at least one of the interval rates (line 10). The adjusting step then adjusts the basal rate based on the total dose and the plurality of interval rates (lines 11 – 12). The delivering step delivers the fluid medication based on the adjusted basal rate and the plurality of interval rates (lines 13 – 14). This amendment is supported in paragraphs [27] – [32], [36] – [37], [44] and [49]. No new matter has been added.

Provisional Rejections Under 35 USC § 101

Claims 1 – 11 have been provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 25 – 35 of copending U.S. Patent Application Serial No. 10/278,769.

It is noted that this are provisional rejections.

Claims 25 – 35 of copending U.S. Patent Application Serial No. 10/278,769 have been withdrawn from consideration in that application and will be canceled prior to issuance of the application.

With the future cancellation of claims 25 – 25 of copending U.S. Patent Application Serial No. 10/278,769, these rejections will be rendered moot.

Rejections Under 35 USC § 102

Rejections in view of Kraegen et al '901

Claims 1 – 4, 6 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,475,901 ("Kraegen et al '901"). These rejections are respectfully traversed.

Kraegen et al '901 discloses an insulin pump that dispenses diabetic control liquids to a patient (Abstract). Liquids are dispensed at a default basal rate, and a "meal rate" to increase delivery at particular times (column 2, lines 45 – 50). The patient may select among three different settings for the basal rate dependent on the patient's anticipated activities in the near-term (column 4, lines 23 – 27). The pump may determine when the amount of liquid delivery per unit time exceeds a maximum or falls below a minimum, and sound an alarm (column 6, lines 8 – 15). A basal rate may be selected by the controller that corresponds to a selected blood glucose level (column 9, lines 59 – 65). However, Kraegen et al '901 does not show, disclose or suggest the ability to set a maximum dose of fluid medication that may be delivered over a period of time, setting a basal rate and a plurality of interval rates, determining a total dose, and then the system adjusting the basal rate so that the total dose does not exceed the maximum dose, and then delivering fluid medication at the adjusted basal rate and the interval rates.

By contrast, claim 1, as amended, requires manually programming a maximum dose, a basal rate and a plurality of interval rates over a specified period of time (lines 4 – 7), the system determining a total dose based on the basal and interval rates (lines 8 – 10), the system adjusting the basal rate so the total dose does not exceed the maximum dose (lines 11 – 12), and delivering fluid medication at the adjusted basal rate and the interval rates (lines 13 – 15). Thus, in a representative example, where the period of time is 24 hours, the basal rate would be adjusted to ensure that the established total does of mediation will be delivered over those 24 hours, regardless of whether the patient in question initiates many interval rate infusions, or few. The difference between the requirements of claim 1, as amended, and Kraegen et al '901 are distinct. While Kraegen et al '901 discloses the patient adjusting the basal rate in the event an alarm sounds, indicating the delivered medication has exceeded an allowable minimum or maximum,

the present invention adjusts the basal rate so as not to exceed the prescribed, desired amount. This establishes that the maximum dose not be exceeded without making requirements on the patient to adjust the basal rate to one of only three discrete settings.

Claim 1, as amended requires adjusting a basal rate so as not to exceed a maximum dose. Kraegen et al '901 discloses sounding an alarm if the total dose moves out of a desired range, but does not show, disclose or suggest adjusting the basal rate to maintain a total dose. Thus, it is respectfully submitted that the rejection of claim 1, as amended, under 35 U.S.C. § 102(b) as being anticipated by Kraegen et al '901 is improper and should be withdrawn.

Claims 2 - 4, 6 and 9 are dependent on claim 1, and as such are subject to all of the limitations of claim 1, as amended. Thus, because the rejection of claim 1, as amended, is improper, it is respectfully submitted that the rejection of claims 2 – 4, 6 and 9 under 35 U.S.C. § 102(b) as being anticipated by Kraegen et al '901 is likewise improper and should be withdrawn.

Claim 12 is dependent on claim 1, and as such is subject to all of the limitations of claim 1, as amended. Thus, because the rejection of claim 1, as amended, is improper, it is respectfully submitted that claim 12 should be in condition for allowance.

New claim 13 requires manually programming a basal rate and a plurality of interval rates (lines 4 – 7) and the system determining a total dose based on the basal rate and the interval rates (lines 8 – 9). When at least one of the interval rates are then adjusted, the system adjusts the basal rate in order to maintain the original total dose (lines 10 – 12), and then delivering the fluid medication at the adjusted basal rate and the interval rates (lines 13 – 14). As noted above, Kraegen et al '901 does not show, disclose or suggest the system adjusting the basal rate at all, to say nothing of adjusting the basal rate in order to maintain the same total dose in the event one of the interval rates is subsequently changed. Thus, Kraegen et al '901 does not show, disclose or suggest all of the limitations of new claim 13, and it is respectfully submitted that claim 13 is in condition for allowance.

Rejections in view of Zalesky et al '078

Claims 1 – 4, 6, 9 and 10 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,389,078 ("Zalesky et al '078"). These rejections are respectfully traversed.

Zalesky et al '078 discloses a programmable infusion pump that combines automatic and demand doses with basal rates (Abstract). A lockout may be triggered to prevent a patient from self-administering too many demand doses as a function of time (column 4, lines 61 – 63). There is a method an apparatus for calculating an effective rate so that fluid is not under-delivered relative to a minimum rate (column 5, line 67 – column 6, line 2). Zalesky et al '078 further calculates a total rate by adding the basal rate to the automatic and demand doses, averaged over time (column 5, line 66 – column 6, line 4). However, Zalesky et al '078 does not show, disclose or suggest the ability to set a maximum dose to be delivered over a period of time, and adjusting the basal rate so that the total dose does not to exceed the maximum dose over that period of time.

By contrast, as has been discussed above, claim 1, as amended, requires manually programming a maximum dose, a basal rate and a plurality of interval rates during a specified period of time (lines 4 – 7), the system determining a total dose based on the basal and interval rates (lines 8 – 10), the system adjusting the basal rate, delivered over the specified period of time, so the total dose does not exceed the maximum dose (lines 11 – 12), and delivering fluid medication at the adjusted basal rate and the interval rates (lines 13 – 15). Thus, in a representative example, where the period of time is 24 hours, the basal rate would be adjusted to ensure that the established total does of mediation will be delivered over those 24 hours, regardless of whether the patient in question initiates many interval rate infusions, or few. The difference between the requirements of claim 1 and Zalesky et al '078 are distinct. While claim 1 requires setting a maximum dose, a basal rate and a plurality of interval rates, determining a total dose based on the basal rate and interval rates, and preventing exceeding the maximum dose by adjusting the basal rate, Zalesky et al '078 does not show, disclose or suggest setting a maximum dose per

unit time, nor does Zalesky et al '078 show, disclose or suggest adjusting the basal rate to so as not to exceed the maximum dose.

Claim 1 requires adjusting a basal rate so as not to exceed a maximum dose. Zalesky et al '078 does not show, disclose or suggest adjusting the basal rate to maintain a total dose. Thus, it is respectfully submitted that the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Zalesky et al '078 is improper and should be withdrawn.

Claims 2 - 4, 6 and 9 are dependent on claim 1, and as such are subject to all of the limitations of claim 1. Thus, because the rejection of claim 1 is improper, it is respectfully submitted that the rejection of claims 2 – 4, 6 and 9 under 35 U.S.C. § 102(b) as being anticipated by Zalesky et al '078 is likewise improper and should be withdrawn.

Claim 12 is dependent on claim 1, and as such is subject to all of the limitations of claim 1, as amended. Thus, because the rejection of claim 1, as amended, is improper, it is respectfully submitted that claim 12 should be in condition for allowance.

New claim 13 requires manually programming a basal rate and a plurality of interval rates (lines 4 – 7) and the system determining a total dose based on the basal rate and the interval rates (lines 8 – 9). When at least one of the interval rates are then adjusted, the system adjusts the basal rate in order to maintain the original total dose (lines 10 – 12), and then delivering the fluid medication at the adjusted basal rate and the interval rates (lines 13 – 14). As noted above, Zalesky et al '078 does not show, disclose or suggest the system adjusting the basal rate at all, to say nothing of adjusting the basal rate in order to maintain the same total dose in the event one of the interval rates is subsequently changed. Thus, Zalesky et al '078 does not show, disclose or suggest all of the limitations of new claim 13, and it is respectfully submitted that claim 13 is in condition for allowance.

Rejections in view of Hartlaub et al '083

Claims 1 – 7, 9 and 10 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2001/0037083 ("Hartlaub et al '083"). These rejections are respectfully traversed.

Hartlaub et al '083 discloses an implantable drug infusion pump that allows a patient to self-administer additional bolus doses (Abstract). The implantable medical device will prevent the patient from administering too many bolus doses (paragraph [0030]). In addition to bolus doses, the implantable drug infusion pump also delivers therapy at a basal rate, of which the medical professional may program two or more, and which the patient may then switch among "that would be acceptable in reaching the daily dosages" (paragraph [0037]). Where too little medication is being delivered over a particular time period "the therapy program may prompt the patient … to use the patient controller to either activate a bolus dose of medication or to use the next highest base rate" (paragraph [0040]). Alternatively, when it appears that too much medication will be delivered, "the patient would be prompted by the notification mechanism to use the patient controller select a higher base rate in an attempt to reduce the amount of future bolus activation requests" (paragraph [0041]). Alternatively, "if the patient is nearing the maximum daily dose then the therapy program could deny further activation requests, activate the smallest programmed does when an activation request is made by the patient or prompt the patient to select the next lowest base rate" (paragraph [0042]). Thus, Hartlaub et al '083 discloses working to prevent the delivery of drugs either above or below a certain range by prompting or inhibiting additional bolus doses, and by prompting the user to change the basal rate to a different setting. However, Hartlaub et al '083 does not show, disclose or suggest not exceeding a maximum dose by adjusting a basal rate dependant on the delivered interval rates.

By contrast, as has been discussed above, claim 1, as amended, requires manually programming a maximum dose, a basal rate and a plurality of interval rates during a specified period of time (lines 4 – 7), the system determining a total dose based on the basal and interval rates (lines 8 – 10), the system adjusting the basal rate, over the specified period of time, so the total dose does not exceed the maximum dose (lines 11 –

12), and delivering fluid medication at the adjusted basal rate and the interval rates (lines 13 – 15). Thus, in a representative example, where the period of time is 24 hours, the basal rate would be adjusted to ensure that the established total does of mediation will be delivered over those 24 hours, regardless of whether the patient in question initiates many interval rate infusions, or few. The difference between the requirements of claim 1 and Hartlaub et al '083 are distinct. While claim 1 requires setting a maximum dose per unit time, and then not exceeding that maximum dose by adjusting the basal rate, Hartlaub et al '083 does not show, disclose or suggest adjusting the basal rate to not exceed a maximum dose. Rather, bolus doses are delivered and a user is prompted to adjust a basal rate to keep delivered drugs within a particular zone.

Claim 1 requires adjusting a basal rate to maintain a total dose. Zalesky et al '078 does not show, disclose or suggest adjusting the basal rate to maintain a total dose. Thus, it is respectfully submitted that the rejection of claim 1 under 35 U.S.C. § 102(e) as being anticipated by Hartlaub et al '083 is improper and should be withdrawn.

Claims 2 – 7, 9 and 10 are dependent on claim 1, and as such are subject to all of the limitations of claim 1. Thus, because the rejection of claim 1 is improper, it is respectfully submitted that the rejection of claims 2 – 7, 9 and 10 under 35 U.S.C. § 102(e) as being anticipated by Hartlaub et al '083 is likewise improper and should be withdrawn.

Claim 12 is dependent on claim 1, and as such is subject to all of the limitations of claim 1, as amended. Thus, because the rejection of claim 1, as amended, is improper, it is respectfully submitted that claim 12 should be in condition for allowance.

New claim 13 requires manually programming a basal rate and a plurality of interval rates (lines 4 – 7) and the system determining a total dose based on the basal rate and the interval rates (lines 8 – 9). When at least one of the interval rates are then adjusted, the system adjusts the basal rate in order to maintain the original total dose (lines 10 – 12), and then delivering the fluid medication at the adjusted basal rate and the interval rates (lines 13 – 14). As noted above, Hartlaub et al '083 does not show, disclose or suggest the system adjusting the basal rate at all, to say nothing of adjusting the basal

rate in order to maintain the same total dose in the event one of the interval rates is subsequently changed. Thus, Hartlaub et al '083 does not show, disclose or suggest all of the limitations of new claim 13, and it is respectfully submitted that claim 13 is in condition for allowance.

Summary

In view of the amendments made and the arguments presented, claims 1 – 13 should be allowable, this application should be in condition for allowance and a notice to that is earnestly solicited.

Respectfully Submitted,

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Date: August 31, 2007

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